DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

m2264n

December 17, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 09

Loren Duescher
Duescher Hilltop Jerseys
East 3470 Highway F
Kewaunee, Wisconsin 54216

Dear Mr. Duescher:

An investigation at your dairy operation located at Kewaunee, Wisconsin, conducted by our investigators on November 2 and 5, 1998, and December 8, 1998, confirmed that you offered a heifer for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about March 25, 1998, you sold a heifer, identified with back tag 369 and ear tag 35 TLW 2539, for slaughter as human food at [redacted] United States Department of Agriculture (USDA) analysis of tissue samples collected from that animal identified the presence of 15.00 parts per million (ppm) sulfadimethoxine in the liver and 17.00 ppm sulfadimethoxine in the muscle. A tolerance of 0.1 ppm has been established for residues of sulfadimethoxine in the edible tissues of cattle (Title 21, Code of Federal Regulations, Part 556.640). The presence of this drug in edible tissues from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling and for assuring that animals medicated

by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from such animals held under such conditions are adulterated.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

JAR/ccl